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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,532	08/03/2001	Endre Markovits Schersl	06965-1001	9018

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 08/08/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/922,532

Applicant(s)

SCHERSL ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**Final Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Double Patenting***

2. The provisional rejection of claims 1-9 under the judicially created doctrine of obviousness-type double patenting over claims 23-35 of copending Application No. 09/772,790 is maintained.

It is noted that applicant requested that a determination on the merits of the present invention and that of 09/772,790 be made before filing of a terminal disclaimer, if necessary.

For this reason and those given in Paper No. 9, the provisional rejection of claims 1-9 under the judicially created doctrine of obviousness-type double patenting over claims 23-35 of copending Application No. 09/772,790 is maintained.

***Claim Rejections - 35 USC § 102***

3. The rejection of claims 1, 3, 4, 5 and 9 under 35 USC 102(b) over Sorkin, Jr. ('393) is maintained.

Applicant argues that the present invention recites compositions comprising "wood alcohols" or a mixture thereof whereas Sorkin teaches a composition comprising rice bran wax, which is a mixture of policosanols. According to applicant, there are

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differences in composition between wood alcohols and plant wax alcohols such as the presence of stanols that are not found in plant sterols derived from vegetable oil.

Applicant's argument was considered but not persuasive for the following reasons.

The claimed invention is a composition **comprising one or more** component selected from the group consisting of "octadecanol, eicosanol, docosanol, tetracosanol and hexacosanol" and **one or more** component selected from the group consisting of " $\beta$ -sitosterol,  $\beta$ -sitosteryl ester of a fatty acid,  $\beta$ -sitostanol,  $\beta$ -sitostanyl ester of a fatty acid, campesterol, campesteryl ester of a fatty acid, campestanol, campestanyl ester of fatty acid, stigmasterol and stigmasteryl ester of a fatty acid". How and/or where one obtains said component(s) would not change the make up of the composition(s). For example, a composition comprising octadecanol and  $\beta$ -sitosterol, wherein the octadecanol is derived from wood alcohol as recited by the instant invention would be identical to a composition comprising octadecanol and  $\beta$ -sitosterol, wherein the octadecanol is derived from rice bran wax. Thus, the recitation of how/where the policosanol is obtained does not lend patentability to the composition. In other words, the claimed composition only requires one or more component(s) derived from wood alcohol not an extract derived from said. As is shown by the prior art, said component(s) can be derived from other sources. It is also noted, that the instant claims do not require the composition comprise a stanol as argued by applicant.

For these reasons and those given in Paper No. 9, the rejection of claims 1, 3, 4, 5 and 9 under 35 USC 102(b) over Sorkin, Jr. ('393) is maintained.

***Claim Rejections - 35 USC § 103***

- 4. The rejection of claims 1-9 under 35 USC 103(a) over Sorkin, Jr. ('393), Maurel et al. ('924) and Perez ('354) in combination is maintained.**

Applicant argues Maurel does not bear reference to the field of invention of either the present invention or the other patents. Applicant also argues the differences in composition between wood alcohols and plant wax alcohols. Applicant's argument was considered but not persuasive for the following reasons.

Applicant's argument and the examiner's response in relation to the differences in compositions between wood alcohols and plant wax alcohols are as discussed above in #3.

In response to applicant's argument that Maurel does not bear reference to the field of invention of the present invention and the other cited references, the examiner notes that the reference is utilized for its teaching of what was known in the art at the time of the present invention as to the utilization of plant sterols. Said teaching bears reference to the field of invention in both the present invention and the cited prior arts.

For these reasons and those given in Paper No. 9, the rejection of claims 1-9 under 35 USC 103(a) over Sorkin, Jr. ('393), Maurel et al. ('924) and Perez ('354) in combination is maintained.

***Conclusion***

- 5. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### ***Telephone Inquiry***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308- 2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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Barbara P. Badio, Ph.D.

Primary Examiner

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August 8, 2003